FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (No. II)	MDL No. 13-2418 (FLW)
UNITED STATES *et al.*, ex rel. ELISA DICKSON, Plaintiffs, v. BRISTOL-MYERS SQUIBB CO., *et al.*, Defendants.	Civ. Action No: 13-1039 (FLW) **OPINION**

WOLFSON, District Judge:

This *qui tam* action, a member case of the Multi-District Litigation, *In re: Plavix Marketing, Sales Practices and Products Liability Litigation*, involves the alleged wrongful marketing and sales of Plavix (clopidogrel bisulfate), a prescription blood thinner manufactured by Defendant Bristol-Myers Squibb Company ("BMS") and marketed in the United States by BMS and Defendants Sanofi-Aventis U.S. LLC, Sanofi U.S. Service Inc., and Sanofi-Synthelabo Inc. (collectively "Sanofi") (collectively "Defendants"). Relator Elisa Dickson ("Relator") brought this case on behalf of the United States and various states, asserting claims under the following statutes: (Count 1) the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733;

(Count 2) Conspiracy under the FCA, 31 U.S.C. § 3729(a), as well as 26 separate state law claims.[1]

Defendants move to dismiss the Third Amended Complaint ("TAC") on the basis that Relator's allegations—namely, that Defendants engaged in false marketing causing physicians to submit claims to Medicaid and Medicare Part D that were not "medically necessary" or "reasonable and necessary"— are insufficient to state a claim under the FCA and the state statutes. As a threshold issue, however, Defendants maintain that Relator's state and federal claims are barred by the

[1] Those causes of actions include: (Count 3) Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*; (Count 4) California False Claims Act, Cal. Gov't Code §§ 12650-12655; (Count 5) Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201(a)(1) and (2); (Count 6) District of Columbia Procurement Reform Act, D.C. Code §§ 2-308.13 to .15; (Count 7) Florida False Claims Act, Fla. Stat. § 68.081–68.090; (Count 8) Hawaii False Claims Act, Haw. Rev. State. §§ 661-12 to -29; (Count 9) Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.01 to .250; (Count 10) Tennessee Medicaid False Claims Act, Tenn. Code. Ann. § 71-5-181 to -185; (Count 11) Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 to .132; (Count 12) Virginia Fraud Against Taxpayers Act, VA Code Ann. §§ 8.01-216.1 to -216.19; (Count 13) Georgia False Medicaid Claims Act, Ga. Code Ann § 49-4-168 *et seq.*; (Count 14) Indiana State False Claims and Whistleblowers Protection Act; Ind. Code. Ann §§5-11-5.5-1 to -18; (Count 15) Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 to .613; (Count 16) Montana False Claims Act, Mont. Code Ann. § 17-8-401 to -412; (Count 17) New Mexico False Claims Act, N.M. Stat. Ann. § 27-14-1 to -15; (Count 18) New York False Claims Act, N.Y. State. Fin. Law § 187 *et seq.*; (Count 19) Massachusetts False Claims Act, Mass. Gen. Laws. Ch. 12 § 5(A); (Count 20) City of Chicago False Claims Act, Municipal Code of Chicago §§ 1-22-010 to -060; (Count 21) New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 to -17; (Count 22) Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 to 1-8; (Count 23) Wisconsin False Claims Act, Wis. Stat. § 20.931; (Count 24) Oklahoma False Claims Act, Okla. Stat. tit. 63 § 5053 to 5053.7; (Count 25) North Carolina False Claims Act, N.C. Gen. Stat. §§ 1.605 to -618, 108A-63; (Count 26) Minnesota False Claims Act, Minn. Stat. § 15.C01 *et seq.*; (Count 27) Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.*; and (Count 28) Connecticut Medicaid False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.*

applicable statute of limitations, and by the doctrine of public disclosure set forth in the FCA.

For the reasons expressed herein, Relator's Motion to Dismiss is **GRANTED** in part and **DENIED** in part. Specifically, the following categories of Relator's claims are dismissed: (1) federal FCA claims based on Medicare Part D; (2) federal FCA claims based on the Medicaid plans of thirty-three states, including the District of Columbia;[2] and (3) claims based on state formularies. The only surviving federal claims are Relator's FCA claims related to the Medicaid plans of the following states: Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington and Wyoming. Additionally, all claims arising under state law are dismissed, except for the following states: Delaware, Montana, Massachusetts, Rhode Island, Oklahoma, North Carolina, and Connecticut. Moreover, Relator has also filed a Motion for Reconsideration of this Court's previous denial of her Motion for Suggestion of Remand. For the reasons stated herein, this motion is **DENIED**.

BACKGROUND

I. Factual Background

The relevant facts alleged in the Third Amended Complaint, which I must take as true for the purpose of this Motion, are as follows.

[2] For the sake of brevity, the Court will not expand upon this aspect of the Court's decision here, as it will be discussed extensively *infra*.

Plavix, clopidogrel bisulfate, is a FDA-approved prescription blood thinner, which is marketed for the treatment of Acute Coronary Syndrome, and used by patients following the occurrence of myocardial infarction, stroke or established peripheral artery disease. *See* TAC at ¶ 1. While under patent, Plavix was BMS's top-selling product, with sales accounting for 30% of its gross revenue ($1.67 billion). *Id.* BMS and Sanofi market Plavix jointly. *Id.* at ¶ 2. Plavix costs approximately four dollars per pill. *Id.* at ¶ 3. Since 1998, the FDA has sent three letters to Sanofi involving the allegedly misleading promotion of Plavix. *Id.* at ¶¶ 4–14.

Relator worked in the pharmaceutical industry for twelve years, and was employed by Sanofi as a sales representative specializing in selling Plavix. *Id.* at ¶ 16. Relator alleges that she was instructed by Sanofi to promote Plavix as having certain characteristics that Sanofi knew were not true. *Id.* at ¶ 19. For example, while trial data found non-significant efficacy in stroke victims, Relator was instructed to promote Plavix as superior to aspirin in stroke patients. *Id.* at ¶ 20. Relator also promoted Plavix as comparably safe to aspirin, based on a study which compared Plavix to a more toxic dose of aspirin not normally prescribed today. *Id.* Relator further alleges that she was instructed to focus sales calls on physicians who wrote significant numbers of prescriptions submitted to government payors. *Id.* at ¶ 22.

In that regard, according to Relator, Defendants engaged in a comprehensive scheme to defraud federal and state governments by illegally and deceptively promoting Plavix. *Id.*at ¶ 23. Relator claims that Plavix is no more effective than aspirin, while being many times more expensive. *Id.* at ¶ 24. Thus, Relator alleges,

Defendants' actions caused states to include Plavix on their Medicaid formularies for indications for which Plavix was not medically necessary. *Id.* Plaintiff further asserts that Medicare Part D requires prescriptions to be "reasonable and necessary" to be reimbursable, and that Medicaid requires prescriptions be "medically necessary" to be reimbursable. *Id.* at ¶ 26. According to Relator, Defendants' false marketing prevented physicians from making an informed decision as to Plavix's reasonable or medical necessity, and therefore caused physicians to submit numerous false claims for reimbursement to Medicaid and Medicare Part D. *Id.* at ¶¶ 27–28.

II. Procedural History

Relator filed the original complaint in the United States District Court for the Southern District of Illinois on March 30, 2011. First and Second Amended Complaints were filed in that court in 2011 and 2012, respectively. Defendants moved to dismiss the Second Amended Complaint in December 2012. On January 30, 2013, the Hon. David R. Herndon, U.S.D.J., denied the Motion in part, and granted it in part, dismissing only a claim on which Relator had requested a voluntary dismissal. On February 14, 2013, the case was transferred to this Court by the Judicial Panel on Multidistrict Litigation. Defendants then filed a Motion for Reconsideration before this Court on the denial of their Motion to Dismiss, on the basis that Judge Herndon's January 30 Order incorrectly assumed that a "reasonable and necessary" standard applied to Medicaid and Medicare Part D. Following a hearing on August 22, 2013, this Court granted the Motion for Reconsideration, vacated the prior denial of the Order to Dismiss with respect to the FCA claims under Medicaid and Medicare Part

D, and granted the Motion to Dismiss with respect to the FCA claims under those programs. The Court granted Relator leave to amend her Complaint. Relator filed the TAC on September 20, 2013; this Motion to Dismiss followed.

DISCUSSION

I. Standard of Review

A. Rule 12(b)(6)

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted, pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. *Evancho v. Fisher*, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Baldwin Cnty. Welcome Ctr. v. Brown*, 466 U.S. 147, 149–50 n. 3 (1984) (quotation and citation omitted). A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" *Bell Atlantic v. Twombly*, 550 U.S. 544, 583 (2007) (quoting *Scheuer v. Rhoades*, 416 U.S. 232, 236 (1974)); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) ("Our decision in *Twombly* expounded the pleading standard for all civil actions.") (internal citations omitted);

Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("*Iqbal* . . . provides the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before *Twombly.*").

Following the *Twombly/Iqbal* standard, the Third Circuit applies a two-part analysis in reviewing a complaint under Rule 12(b)(6). First, a district court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. *Fowler,* 578 F.3d at 210. Second, a district court must determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief." *Id.* A complaint must do more than allege the plaintiff's entitlement to relief. *Id.* However, this standard "'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element.'" *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 127 U.S. at 1965); *see also Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim . . . . The pleading standard is not akin to a probability requirement, . . . to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citations omitted)). Nonetheless, a court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429–30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has

been presented. *Hedges v. U.S.*, 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. *Southern Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999).

B. Rule 12(b)(1)

A defendant may move to dismiss a claim for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). There is no presumption of truthfulness that attaches to the allegations of the complaint when determining a challenge to the court's subject matter jurisdiction. *Mortensen v. First Federal Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Once a 12(b)(1) challenge is raised, the plaintiff bears the burden of demonstrating the existence of subject matter jurisdiction. *See McCann v. Newman Irrevocable Trust*, 458 F.3d 281, 286 (3d Cir. 2006). A Rule 12(b)(1) motion to dismiss is treated as either a "facial or factual challenge to the court's subject matter jurisdiction." *Gould Electronics, Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). Under a facial attack, the movant challenges the legal sufficiency of the claim, and the court considers only "the allegations of the complaint and documents referenced therein and attached thereto in the light most favorable to the plaintiff." *Id.* Under a factual attack, however, "the challenge is to the actual alleged jurisdictional facts." *Id.* "Because at issue in a factual 12(b)(1) motion is the trial court's jurisdiction -- its very power to hear the case -- there is substantial authority

that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Mortensen*, 549 F.2d at 891.

II. Public Disclosure Bar[3]

At the outset, I note that Defendants' motion to dismiss for lack of subject matter jurisdiction is based on the public disclosure bar of the FCA, 31 U.S.C. § 3730(e)(4). This is an attack on the "actual alleged jurisdictional facts," and therefore, the Court is permitted to weigh the evidence presented. The FCA bars *qui tam* actions where the allegations have previously been publically disclosed. However, the public disclosure bar was amended in 2010 by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The original statute contained a jurisdictional limitation, stating "No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions . . . ." 31 U.S.C. § 3730(e)(4). The amended statute, however, merely mandates dismissal: "The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . ." 31 U.S.C. § 3730(e)(4)(A). Additionally, changes were made to the sections defining the sources that constitute a public disclosure, *see id.* at § 3739(e)(4)(A)(i)–(iii), and to the definition of "original source." *Id.* at § 3739(e)(4)(B).

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[3] This issue was raised in Defendants' Motion to Dismiss the Second Amended Complaint; Chief Judge Herndon, however, declined to address the issue, stating that "the record in this case is not adequate to make such a factual determination at this stage in the proceedings." January 2013 Memorandum and Order at 7. I will, nevertheless, resolve this issue here.

Both parties primarily analyze their respective arguments under the pre-2010 statute, though Defendant asserts that "the result is the same under the post-2010 FCA because Relator has failed to allege sufficient facts to demonstrate that she had knowledge independent of the publicly disclosed allegations." Def. Br. at 22. On the other hand, Relator briefly discusses "claims governed by the post-PPACA statute,"[4] Rel. Opp. at 31 n. 82. To the extent that the TAC alleges conduct which resulted in false claims being made prior to the 2010 amendments, I agree that the pre-2010 statute should apply.

The Supreme Court has declined to apply the amended statute in cases filed prior to the Amendment because "[t]he legislation makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates petitioners' claimed defense to a *qui tam* suit." *Graham Cnty. Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n. 1 (2010). While Relator's case here was filed after the 2010 amendment, the question of a statute's retroactive effect looks to the date of the underlying conduct, not the date a complaint was filed. *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 916 (4th Cir. 2013) (citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994) ("[T]he legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place . . . ."). For that reason, the Fourth Circuit declined to

[4] Specifically, Relator argues that "for claims governed by the post-PPACA statute, Defendants' primary reference" namely, the Complaint filed in *Hall v. Bristol-Myers Squibb Co.*, Civ. No. 06-5203 (D.N.J. May 1, 2009), "along with Defendants Exhibits H and I do not constitute a public disclosure because they are not federal cases where the Government is a party."

apply the 2010 amendment to a case where the underlying conduct took place prior to the amendments. *Id.* Similarly, with regard to false claims which occurred prior to 2010, I find that the pre-amendment statute applies. However, I note that the allegations in the TAC appear to also include conduct by Defendants which occurred after the 2010 amendment to the FCA. *See* Compl. ¶¶ 118–19 (discussing studies published in 2010). I therefore also must discuss the application of the post-2010 statute.

According to Defendants, the allegations in Relator's complaints are supported by, or substantially similar to, allegations which were previously disclosed by the news media, federal government reports, or previously filed lawsuits. Defendants further contend that Relator is not an original source of the information, because she has not pleaded how and when she obtained direct and independent knowledge of the alleged fraud.

In response, Relator maintains that she is an original source of the information, because she was a sales representative who participated in Defendants' alleged scheme to defraud the government. Rel. Opp. at 29. Relator additionally argues that there was no public disclosure because the "critical element" of fraud was not disclosed in the publicly disclosed sources. *Id.* at 30. Finally, Relator contends that the allegations in the TAC are not "based on" or "substantially similar" to the prior disclosures because her "eyewitness accounts provide far more than the general notion of misconduct that can be gleaned from public sources." *Id.* at 34–35.

A. Pre-2010 Claims

The pre-2010 statute provided that

> [n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4). The statute further defined "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." *Id.*

According to the Third Circuit, the public disclosure bar requires a court to determine whether a disclosure "issue[d] from a source or occur[ed] in a context specifically recognized by the Act" and is "sufficient to support the conclusion that the information contained therein is now public within the meaning of the Act." *United States ex. rel. Paranich v. Sorgnard*, 396 F.3d 326, 332–33 (3d Cir. 2005). A disclosure is "sufficiently public" if the information therein "would have been equally available to strangers to the fraud transaction had they chosen to look for it as it was to the relator." *Id.* (internal quotation marks and citation omitted). In addition, the Third Circuit has held that "a complaint in a civil action falls into the context of 'criminal, civil, or administrative hearings' and is sufficiently public within the meaning of the Act to constitute a public disclosure." *Id.* at 334.

Defendants argue that the following public disclosures bar Relator's claims: the Second Amended Complaint filed in *Hall v. Bristol-Myers Squibb Co.*, Civ. No. 06-5203 (D.N.J. May 1, 2009), Watson Cert., Ex. B; a newspaper article published in the Madison-St. Clair Record on November 4, 2010, *id.* at Ex. C; a report by the American Association for Justice, published online March 1, 2007, *id.* at Ex. E; a newspaper article published in the St. Petersburg Times and Associated Press on January 20, 2005, *id.* at Ex. F; and an article published in Internal Medicine News on March 1, 2005, *id.* at Ex. G. As to the first inquiry—whether a document constitutes a public disclosure—I find that the *Hall* Complaint is a public disclosure as defined by the Third Circuit in *Paranich*. Similarly, the remaining documents clearly fall within the "news media" category of the statute, and the information contained therein was available to strangers to the fraud.

The next question is whether the TAC is "based on" these disclosures; "based on" is defined as "supported by" or "substantially similar to." *United States ex rel. Atkinson v. PA Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007). The Third Circuit has followed the D.C. Circuit in using "an algebraic representation of the nature and extent of disclosure required to raise the jurisdictional bar." *Id.* That is "[I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements"; then, in order to "draw an inference of fraud, both a misrepresented [X] and a true [Y] state of facts must be publicly disclosed." *Id.* Thus, "if either Z (fraud) or both X (misrepresented facts) and Y (true facts) are disclosed by way of a listed source, then

a relator is barred from bringing suit under § 3730(e)(4)(A) unless [s]he is an original source." *Id.*

The public sources, including the *Hall* Complaint, cited above, discuss the findings of a study known as "CAPRIE," which compared Plavix to aspirin, and the "Chan study," which compared the effects of Plavix and aspirin on patients who previously had stomach ulcers, as well as FDA letters sent to Defendants; all the facts from the sources are presented in the TAC.[5] *See* Watson Cert, Ex. D (comparing *Hall* Complaint, TAC, and media reports). Essentially, these sources indicate that Plavix is no more effective or safer than aspirin. *Id.* To use the algebraic formula presented by the Third Circuit, the misrepresented facts (X) are Defendants' representations that Plavix is more effective and safer than aspirin; the true facts (Y) are that Plavix is neither more effective nor safer than aspirin.[6] Both sets of facts are alleged in the public disclosures provided by Defendants. Thus, I find that the TAC is substantially similar to, and therefore based on, these public disclosures.[7]

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5 The Court makes no comment on the merits of Relator's allegations regarding these studies.

6 Relator asserts that the "critical elements" of fraud were not alleged in these sources, namely that Defendants acted knowingly. Rel. Opp. at 30–31. However, the formulation given by the Third Circuit does not require that the public disclosures reveal any knowledge to implicate the public disclosure bar, nor does Relator cite to any cases to support her position.

7 I note that the TAC alleges additional fraudulent conduct not present in the public disclosures, namely that Defendants instructed Relator to present data from a different study, entitled "PRoFESS" (TAC Ex. E) in such a way as to make physicians believe that another drug, Aggrenox, was inferior to Plavix. TAC at ¶ 21. However, as discussed further *infra*, these allegations do not alter the determination that

Although Relator's complaint is substantially similar to the information in the public disclosures, Relator argues that she is an original source of the information. "To be an original source, a relator's knowledge must be both direct and independent." *Atkinson*, 473 F.3d at 520. "Independent knowledge" is defined as "knowledge that does not depend on public disclosures," while "direct knowledge" is defined as "knowledge obtained without any intervening agency, instrumentality or influence: immediate." *Id.* (internal quotation marks and citation omitted). A party has direct knowledge of a fraudulent scheme when the party was involved in the scheme. *Paranich*, 396 F.3d at 336. However, "[i]f the relator's knowledge of the element is based solely on a § 3730(e)(4)(A) public disclosure, the relator is not an original source." *Id.* Moreover, "[t]o establish original source status knowledge, a *qui tam* plaintiff must allege specific facts—as opposed to mere conclusions—showing exactly how and when he or she obtained direct and independent knowledge of the fraudulent acts alleged in the complaint." *Id.*

Here, Relator alleges that she had direct and independent knowledge of Defendants' alleged fraud because she was involved in it. Specifically, the TAC states that Relator worked as a sales representative at Sanofi beginning in 2003. TAC at ¶ 16. Relator alleges that she was trained and instructed "to confuse physicians and to focus sales calls on physicians and prescribers whose patients relied on Medicaid and Medicare." *Id.* at ¶ 110. Relator specifically alleges that she received the CAPRIE

Relator's allegations are substantially similar to the information revealed in the public disclosures.

Road Map for training purposes, "which revealed Plavix's non-significant efficacy data, and yet was instructed by BMS/Sanofi to promote Plavix in direct contradiction to its results." *Id.* at ¶ 111. She also states that she was "instructed to present the data from yet another study [the PRoFESS Study, TAC, Ex. E] in a manner designed to confuse physicians and make them believe that [another drug] was inferior to Plavix." *Id.* at ¶ 21.

Based on these allegations, Relator has sufficiently alleged that she is an independent source of the information revealed in the public disclosures. Indeed, Relator had direct knowledge of Defendants' alleged fraudulent scheme because she was involved in it. Moreover, Relator was given the CAPRIE study independently of the public disclosures—in fact, she claims to have been given the study by Defendants themselves, as part of her training. While Defendants argue that Relator "does not claim direct or independent knowledge of any false statements made to any particular physician," Def. Repl. at 8, this does not undermine Relator's status as an original source. *See Atkinson*, 473 F.3d at 520.

Thus, while the TAC is "based on" public disclosure of allegations within the meaning of the pre-2010 version of 31 U.S.C. § 3730(e)(4)(A), I find that Relator is an original source of the information. As such, the public disclosure bar does not apply to prohibit allegations of Defendant's conduct prior to 2010, and therefore the 12(b)(1) motion is denied on that basis.

B. Post-2010 Conduct

Because the TAC also alleges that Defendants' allegedly fraudulent conduct continued after 2010, I also determine whether Relator's claims based on that conduct must be dismissed under the updated public disclosure bar.

The post-2010 statute states that:

> The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). An individual may be an "original source" in two ways: first, if the individual "prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" or, second, if the individual "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and . . . has voluntarily provided the information to the Government before filing an action under this section." *Id.* at § 3730(e)(4)(B).

The first question, again, is whether the sources cited by Defendants are "public disclosures." Under the current definition of public disclosure, all of the news

articles cited by Defendants remain public disclosures, as they are "from the news media." The *Hall* complaint, however, is not a public disclosure as that term is currently defined, because the Government was not a party to that action.

The second question, under the amended statute, is whether those public disclosures contain "substantially the same allegations or transactions as alleged in the action or claim." Again, as discussed above, both the public disclosures and the TAC describe the findings of the CAPRIE and Chan studies. These claims are "substantially the same." The TAC additionally alleges that Defendants instructed Relator to present data from the "PRoFESS" study (TAC, Ex. E) in such a way as to make physicians believe that another drug, Aggrenox, was inferior to Plavix. TAC at ¶ 21. However, the statute does not require that the allegations be identical. *See United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 814 (11th Cir. 2015) (stating that "the significant overlap between [the relator's] allegations and the public disclosures is sufficient to show that the disclosed information . . . is substantially similar to the allegations in the complaint."). I therefore find that the addition of the PRoFESS study does not alter the conclusion that Relator's allegations are "substantially the same" as those made in the prior disclosures.

The final question, then, is whether Relator is an "original source." Relator does not allege that she informed the government of the information contained in the TAC prior to the public disclosures. Thus, only the second ground applies and, correspondingly, Relator must show that her knowledge "is independent of and materially adds to the publicly disclosed allegations or transactions." I have already

found that Relator's knowledge was independent of the public disclosures. I must therefore determine whether Relator's information "materially adds" to the information in the public disclosures.

There is scant case law on the definition of the phrase "materially adds" in the amended FCA statute. The Eleventh Circuit has found that a relator is not an original source where the information in the public disclosures was "sufficient to give rise to an inference" of illegality without the Relator's additional facts. *Osheroff*, 776 F.3d at 815. Similarly, the Eighth Circuit has held that where the "key facts" to an FCA claim have already been "thoroughly revealed," the relator's knowledge, "even if gained early and independently," does not "materially contribute[] anything of import to the public knowledge about the alleged fraud." *United States ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 694 (8th Cir. 2014). The Eastern District of Virginia applied the public disclosure bar where "all essential elements of the . . . scheme were disclosed," and "relators' knowledge appears to add only illustrative examples of the specific behavior that the [prior disclosure] describes with specificity." *United States ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 933 F. Supp. 2d 825, 843 (E.D. Va. 2013). In contrast, the District of Massachusetts found that a relator qualified as an original source when prior disclosures had focused on "the fraud committed on patients and doctors," and the relator's suit "provided information on the alleged fraud on the government for the first time." *United States ex rel. Hagerty v. Cyberonics, Inc.*, ___ F. Supp. 2d ___, ___, 2015 WL 1442497, at *16 (D. Mass. Mar. 31, 2015).

Here, Relator asserts that she "is the first person to inform the government that Defendants affirmatively defrauded the government, knew the truth about Plavix, [and] disregarded that truth." Rel. Opp. at 33. Indeed, Relator's Complaint, unlike the news articles, alleges that Defendants were aware that the claims their salesforce were making about Plavix were false. *See* TAC at ¶ 21. Moreover, the TAC states that Defendants explicitly instructed their sales force to "focus sales calls on physicians who wrote significant numbers of prescriptions for patients covered by certain Government Payors." *Id.* at ¶ 22. Indeed, based on Relator's allegations, Relator has "provided information [regarding] the alleged fraud on the government for the first time." *Hagerty*, 2015 WL 1442497, at *16. These allegations, which tend to show that Defendants had knowledge that their claims were false and were intended to have physicians make false claims to the government involving Plavix prescriptions, provide "essential elements of the fraudulent scheme" which were missing from the prior disclosures. *See id.* Taken together, these facts materially add to the previously disclosed information. In addition, Relator sufficiently alleges in the Complaint that she voluntarily provided the information contained in the TAC to the Government prior to filing the action, as required by 31 U.S.C. §§ 3730(b) and (e). *See* TAC at ¶ 108. Accordingly, Relator also qualifies as an original source under the post-2010 statute.

Having determined that Relator is an original source under both the pre- and post-2010 statutes, I find that the public disclosure bar does not apply in this case.

III. The False Claims Act

Defendants advance several arguments in support of their dismissal motion regarding Relator's claims under the FCA: first, Defendants argue that, on their face, Relator's allegations that Defendants' marketing caused physicians to make false certifications about Plavix's efficacy or necessity for treatment is insufficient to state a claim; second, Defendants argue that Medicaid and Medicare Part D cannot deny reimbursement of a covered prescription because FDA approval of a particular drug is sufficient to render a drug "reasonable and necessary" under these government programs when such a drug is prescribed for its on-label use; and finally, Defendants assert that Relator's allegations regarding the state formularies are insufficient to state a claim under the FCA. After discussing the law applicable to the False Claims Act, I will address each argument in turn.

A. Applicable Law

The FCA imposes civil liability on any person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1). This Act was amended in 2009; prior to the amendment, the statute imposed liability on any person who "(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval" or "(2) knowingly makes, uses, or causes

to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(1)–(2) (amended 2009).[8]

"A plaintiff, in order to establish a prima facie FCA violation under section 3729(a)(1), must prove that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304–05 (3d Cir. 2011). A false claim under the FCA may be either "factually false"—"when the claimant misrepresents what goods or services that it provided to the Government"— or "legally false"—"when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* at 305. Additionally, within the false certification context, there are two categories, express and implied. *Id.* An entity makes an express false certification when it "falsely certif[ies] that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds," while an entity makes an implied false certification when it "seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Id.*

I note that the TAC asserts only legally false claims, as the claimants provided the goods or services for which the claims were made, and the TAC relies on an implied false certification theory. In that regard, The Third Circuit has stated that

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8 The amendments to the statute do not affect the analysis here.

the implied false certification theory of liability "should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs." *Id.* at 307. Furthermore, in order to make a claim for an implied false certification, "it is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but also that payment of the federal funds was in some way conditioned on compliance with those regulations." *Id.* (citing *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 304 (3d Cir. 2008)). That is, "a plaintiff must [allege] that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Id.*

B. Facial Viability of the FCA Claims

I first address the parties' arguments based on the holding in *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295 (3d Cir. 2011). Defendants assert that the allegations in the TAC are insufficient on their face to state a claim for a violation of the FCA. According to Defendants, Medicaid and Medicare Part D are required to reimburse for Plavix prescriptions which are prescribed for indications approved by the FDA, regardless of marketing or the doctor's reasons for the prescription; indeed, Relator concedes that the Plavix prescriptions here were for indications approved by the FDA. Therefore, because the submitted claims were for prescriptions for indications which were FDA-approved, Defendants argue, there can be no FCA liability. On the other hand, Relator argues that the marketing techniques

did not themselves constitute false claims, but that the marketing caused claims to be submitted for payment which did not comply with the federal and state conditions for payment.

Both parties rely on the Third Circuit's decision in *Wilkins.* In that case, a relator filed a *qui tam* action alleging that the defendants, organizations which provided services under Medicare, violated the FCA by offering physicians illegal kickbacks and that the defendants there violated Medicare marketing rules. *Wilkins,* 659 F.3d at 300. The circuit court held that the allegations that the defendants "violated the [marketing] regulations do not state a plausible claim for relief under the FCA inasmuch as the Government's payments of appellees' Medicare claims were not conditioned on their compliance with the marketing regulations." *Id.* at 308. In that regard, the court "distinguished between regulations which are conditions of participation in the Medicare programs and conditions of Government payment of Medicare funds." *Id.* at 309. "'Conditions of participation . . . are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program,' while '[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.'" *Id.* (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008)). The court reasoned that "the fundamental flaw in appellants' allegations is that the amended complaint does not cite to any regulation demonstrating that a participant's compliance with

Medicare marketing regulations is a condition for its receipt of payment from the Government." *Id.* at 309–10.

Here, in contrast, Relator has alleged that Defendants caused physicians to make implied false certifications about the medical necessity of Plavix. According to the Complaint, prescription drugs must be "reasonable and necessary" to be covered by Medicare Part D, *see* TAC at ¶¶ 44–45, and all fifty states have established limits on Medicaid requiring services to be medically necessary. *See id.* at ¶¶ 52–102. As alleged, the limits on Medicare and Medicaid regarding medical necessity are necessarily conditions of payment, not conditions of participation. *Wilkins*, 659 F.3d at 309. Thus, contrary to Defendant's contention, Plaintiff's allegations, on their face[9], are different from those asserted in *Wilkins*.

C. "Reasonable and Necessary" or "Medically Necessary" Conditions for Payment

1. *Medicare Part D*

The thrust of Relator's position with respect to her FCA claims under Medicare Part D is that Defendants' fraudulent marketing of Plavix caused physicians to make false certifications when requesting reimbursements in connection with prescribing Plavix for its on-label use. Specifically, Relator argues that Defendants represented to physicians that Plavix was the "only option for effective patient care in a host of contexts." However, Relator alleges that there were other drugs, such as Aspirin, as effective – if not more effective – than Plavix at a far lower cost. Thus, prescribing

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[9] Defendants' argument that Medicare and Medicaid do not, in fact, place such limits on services will be addressed *infra.*

Plavix for its on-label use, Relator reasons, was not "reasonable and necessary" or "medically necessary." To illustrate, Relator names four[10] Medicare Part D plans which require that a drug be "medically necessary," which is defined as "reasonable and necessary for treatment" in order to be covered. TAC at ¶ 45.

On other hand, Defendants argue that under Part D, prescription drug plans are *permitted* to exclude from coverage drugs which are not "reasonable and necessary," but argue that Relator has not alleged that any such plan has restricted coverage of Plavix. Def. Br. at 10. Absent any exclusions, Defendants argue, when physicians prescribed Plavix for its on-label, FDA approved use, such a prescription should be considered "reasonable and necessary" under Medicare. In light of the parties' arguments, the question before the Court centers on the definition of "reasonable and necessary" in the Medicare statute.

It is true that the Medicare statute permits reimbursement only for medical treatments which are "reasonable and necessary." 42 U.S.C. § 1395y. Relator cites to a number of cases that dealt with the reasonableness of prescribing off-label drugs in the context of Medicare, but, as I will discuss further, *infra,* none of those cases address how "reasonable and necessary" is defined for ***on-label*** prescription drugs. Tellingly, the Court's research did not reveal any case law on that issue, nor has Relator supported her position with any authority. As a result, this Court must examine the statutory language of Medicare and the FDA approval scheme, to

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10 Although the TAC only names four plans, it also notes that "[b]ecause Medicare Part D is privatized, the number of sponsor plans is extremely voluminous." TAC at ¶ 45 n. 37.

determine whether there is any circumstance in which a prescription drug would not be "reasonable and necessary" when that drug is prescribed by a physician for a FDA approved, on-label use.

To begin, Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. *See Heckler v. Ringer*, 466 U.S. 602, 605 (1984). The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). *See id.* Four major components make up the Medicare program: (1) Part A, the hospital insurance benefits program, 42 U.S.C. §§ 1395c, 1395d; (2) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services, 42 U.S.C. §§ 1395j, 1395k, 1395l; (3) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries, 42 U.S.C. § 1395w–21–28, *et seq.*; and (4) Part D, the voluntary prescription drug benefit program. 42 U.S.C. § 1395w–101, *et seq.* Here, Relator's FCA claims are premised on Medicare Part D.

Medicare Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108–173, 117 Stat. 2066, which set up a voluntary prescription drug benefits program for Medicare enrollees. *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F.Supp.2d 125, 131 (E.D. Pa. 2012). Unlike Parts A and B, Medicare Part D is based on a private market model, wherein

Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans. *See United States ex rel Fox Rx, Inc. v. Omnicare, Inc.*, 38 F. Supp. 3d 398, 402-403 (S.D.N.Y. 2014). Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan ("PDP"), a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan ("MA–PD plan"), a Program of All–Inclusive Care for the Elderly ("PACE") organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. *See* 42 C.F.R. § 423.4; *Spay*, 913 F. Supp. 2d at 131.

Part D plan sponsors subcontract with pharmaceutical entities to provide drugs to beneficiaries, including pharmacy benefit managers ("PBM") who provide drugs through mail order and pharmacies. *See Spay*, 913 F. Supp. 2d at 133. As a condition for payment from CMS, the sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. *See* 42 C.F.R. § 423.505(k)(1). A subcontractor entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. *See* 42 C.F.R. § 423.505(k)(3). Indeed, the sponsors and their subcontractors must contractually agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. *See* 42 C.F.R. § 423.505(h)(1); 42 C.F.R. § 423.505(i)(4)(iv).

With respect to coverage, a plan sponsor must provide qualified prescription drug which includes "standard prescription drug coverage" or "alternative prescription drug coverage" with at least actuarially equivalent benefits. *See* 42 U.S.C. § 1395w–102; 42 C.F.R. § 423.104(c). The requirements for standard or alternative prescription drug coverage relating to deductibles, benefit structure, initial coverage limits, out-of-pocket expenditures, etc., are set out in the Medicare Statute and its regulations. *See* 42 U.S.C. § 1395w–102(b); 42 C.F.R. § 423.104(d)(3). Plans may also provide supplemental prescription coverage, which can include reductions in cost-sharing (such as deductibles or coinsurance percentages) or covering certain drugs that would qualify as covered Part D drugs if they were not among the drugs described at 42 U.S.C. § 1396r–8(d)(2), (d)(3) and excluded from the definition of a Part D drug at 42 U.S.C. § 1395w–102(e)(2)(A).

More specifically, Part D covers a range of outpatient prescription drugs, which previously had been covered only in select instances. *Kilmer v. Leavitt*, 609 F. Supp. 2d 750, 751 (S.D. Ohio 2009). However, a Part D plan sponsor need not provide coverage for a Part D drug that is "not reasonable and necessary" for circumstances specified in the statutory framework or that is not prescribed in accordance with the plan or the Medicare Act. *See* 42 U.S.C. §§ 1395w-102(e)(3) and 1395y(a); *Kilmer*, 609 F. Supp. 2d at 751. Rather, to qualify for coverage, an outpatient prescription drug must be used for a medically accepted indication, *see* 42 U.S.C. §§ 1395w-102(e)(1), (e)(4), which means that it can be used for treatment purposes, *inter alia*, approved under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301

et seq. *See* 42 U.S.C. § 1396r-8(k)(6)("The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the [FDCA] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section."). Indeed, under Medicare, "Covered part D drug" is defined as "a drug that may be dispensed upon a prescription," 42 U.S.C. § 1395w-102(e)(1)(A), that is "approved for safety and effectiveness as a prescription drug under section 505 or 507 of the [FDCA]." 42 U.S.C. § 1396r-8(k)(2)(A)(i).

Moreover, regulations promulgated by the Secretary further clarify the scope of what is considered a Part D drug. Title 42, Code of Federal Regulations, section 423.100, states, in relevant part:

> Part D drug means—
>
> > (1) Unless excluded under paragraph (2) of this definition, any of the following if used for a *medically accepted indication* (as defined in [42 U.S.C. § 1395w-102(e)(4)])-
> >
> > > (i) A drug that may be dispensed only upon a prescription and that is described in sections [42 U.S.C. § 1396r-8(k)(2)(A)].

42 C.F.R. § 423.100 (emphasis added).

Based on the above-outlined statutory scheme, a reasonable and necessary covered drug under Part D includes a drug prescribed for uses that are approved by the FDA, i.e., on-label use. *See Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 907 (9th Cir. 2014). Indeed, a drug prescribed for its on-label use -- by definition -- means that the prescription is medically reasonable for its intended purpose by virtue of the FDA approval process. As the Supreme Court has explained, the FDA

approval process of a new drug is "both onerous and lengthy." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). Under the FDCA, 21 U.S.C. § 301, *et seq.*, drug manufacturers must gain FDA approval before marketing any drug in interstate commerce. *See* 21 U.S.C. § 355(a). In the case of a new brand-name drug, such as Plavix, FDA approval can be secured only by submitting a new-drug application ("NDA"). The application is a compilation of materials that must include "full reports of [all clinical] investigations," 21 U.S.C. § 355(b)(1)(A), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source," 21 C.F.R. §§ 314.50(d)(2) and (5)(iv); *see Bartlett*, 133 S. Ct. at 2470-71 (explaining the FDA approval process). The NDA must also include "the labeling proposed to be used for such drug," 21 U.S.C. § 355(b)(1)(F); 21 CFR § 314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. § 314.50(d)(5)(viii); § 314.50(c)(2)(ix).

Importantly, the FDA may approve an NDA only if it determines that the drug in question is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U. S. C. § 355(d); *Bartlett*, 133 S. Ct. at 2470. In order for the FDA to consider a drug safe, the drug's "probable therapeutic benefits must outweigh its risk of harm." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U. S. 120, 140 (2000). In that regard, "Congress made its 'purpose' plain in authorizing the FDA--not [] tort juries--to determine when and under what circumstances a drug is 'safe.'" *Wyeth v. Levin*, 555 U.S. 555, 607 (2009). And, in that

connection, "[w]here the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' [the] conflict preemption cases prohibit any State from countermanding that determination." *See, e.g., Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (after the FDA has struck "a somewhat delicate balance of statutory objectives" and determined that petitioner submitted a valid application to manufacture a medical device, a State may not use common law to negate it).

Significantly, after the FDA approves a drug, "the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug, *see* 21 C.F.R. § 314.80, and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug." *Wyeth*, 555 U.S. at 608 (citing 21 U.S.C. § 355(k)). If the FDA finds that the drug is not "safe," the agency "shall" withdraw its approval of the drug. *See* 21 U.S.C. § 355(e). The FDA also "shall" deem a drug "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

From a plain reading of the Medicare statute regarding the Part D prescription drug coverage, I find that a FDA approved drug that is prescribed for its on-label use is "reasonable and necessary." I come to this conclusion because, for one, the statute is explicit in stating that one of the "medically accepted indications" for a prescribed drug includes any use that has been approved by the FDA. *See* 42 U.S.C. § 1396r-8(k)(6)("The term 'medically accepted indication' means any use for a covered

outpatient drug which is approved under the [FDCA] . . . ."). And, the Regulations accompanying the Medicare requirements in this context mirror the definition of "medically accepted indication" as it appears in § 1396r-8(k)(6). *See* 42 C.F.R. § 423.100. Moreover, the hallmark of the "reasonable and necessary" requirement under Medicare Part D is the effectiveness and safety of a particular prescription drug. *See* 42 U.S.C. § 1396r-8(k)(2)(A)(i).[11] The FDA approval process -- as outlined above -- ensures that an approved drug meets the "reasonable and necessary" standard. Thus, by operation of the Medicare statute, this Court holds that a FDA approved drug that has been prescribed for its on-label use is necessarily covered under Medicare Part D. [12] *See United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014)("[t]o qualify as a 'covered outpatient drug' as defined in the Medicare and Medicaid statutes, a drug merely must be approved by the FDA.").

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[11] Relator cites to *Almy v. Sebelius*, 749 F.Supp. 2d 315, 330 (D. Md. 2010), for the general proposition that "just because a drug is 'FDA-approved' does not mean that it is 'reasonable and necessary.'" Relator's reliance on *Almy* is misplaced, because that case dealt with CMS's determination whether a particular piece of medical equipment is covered under *Medicare Part B*. This is significant since Part B explicitly provides CMS with the discretion to make certain safety determinations as to medical equipment and CMS does not have the same type of discretion under Part D for prescription drugs.

[12] Of course, if a doctor were to give a prescription to a patient who did not require medication at all, such a prescription would not be "reasonable and necessary." Plaintiff, however, has not alleged that Defendants' marketing caused Plavix to be prescribed to patients who did not need such a drug.

My conclusion in this regard in consistent with the findings of those courts that have dealt with Part D drugs that have been prescribed for "off-label" purposes. At the outset, I note that "off-label" use is the use of a particular drug "for some other purpose than that for which it has been approved by the FDA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 27-28 (1st Cir. 2013)("[o]ff-label use marketing is for those conditions or diseases not included in the official label approved by the FDA."). In the context of Medicare Part D, numerous courts have been called upon to resolve the issue whether drugs prescribed for their off-label uses are "reasonable and necessary." *See, e.g.*, *United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357, 369 (E.D. Pa. 2014); *United States ex rel. Cestra v. Cephalon, Inc.*, Civ. No. 14-1842, 2015 WL 3498761, at *8 (E.D. Pa. June 3, 2015); *United States ex rel. Petratos v. Genentech, Inc.*, Civ. No. 11-3691, 2014 WL 7331945, at *4 (D.N.J. Dec. 18, 2014); *United States ex rel. Simpson v. Bayer Corp.*, Civ. No. 05-3895 JLL, 2013 WL 4710587, at *11 (D.N.J. Aug. 30, 2013); *see also United States ex rel. Brown v. Celgene Corp.,* Civ. No. 10-3165-GHK SSX, 2014 WL 3605896, at *4 (C.D. Cal. July 10, 2014); *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, Civ. No. 1:09-1086 (AJT), 2011 WL 2182422, at *3 (E.D. Va. May 4, 2011). These courts' decisions are in unison that if the particular use of the drug is supported by a listing in a major drug compendium,[13] -- even if the use is for an off-label purpose -- that drug may fall

[13] 42 U.S.C. § 1396r-8(k)(6) cites to § 1396r-8(g)(1)(B)(i), which lists three approved compendia: "(I) American Hospital Formulary Service Drug Information;

within the "reasonable and necessary" standard of Medicare. *See, e.g.*, *Simpson*, 2013 U.S. Dist. LEXIS 124928, at *35-*36. Significantly, this finding is taken from, and supported by, the definition of "medically accepted indication," under 42 U.S.C. § 1396r-8(k)(6), *see Bergman*, 995 F. Supp. 2d at 369, which definition also includes any drug approved by the FDA. *See* 42 U.S.C. § 1396r-8(k)(6). Simply put, in those courts' view, a "reasonable and necessary" prescription is equivalent to one given for "a medically accepted indication." *See, e.g., Cestra*, 2015 WL 3498761, at *8 ("Whether prescribing a drug for a particular condition is reasonable and necessary is typically determined by considering whether the drug is prescribed for a 'medically accepted indication' that is reimbursable under Medicare and Medicaid."). And, because a medically accepted indication is also equivalent to a use of a drug that is approved by the FDA, by definition, any on-label drug prescription is, under the statute, reasonable and necessary.

Accordingly, because Relator has not alleged that Plavix is excluded from Medicare Part D coverage, or that Plavix was not prescribed for any purpose other than its on-label use, this Court finds that as a matter of law, any prescription of Plavix, written for its on-label use during the time period alleged, was reasonable and necessary under Medicare Part D. Consequently, Plaintiff cannot a state a claim under the FCA in this context.

2. *Medicaid*

(II) United States Pharmacopeia-Drug Information (or its successor publications); and (III) the DRUGDEX Information System." *See Bergman*, 995 F. Supp. 2d at 369.

Under Medicaid, Relator's position is two-fold; first, Relator argues that Medicaid requires that drugs be "medically necessary" in order to be covered, and that Defendants' misrepresentations caused physicians to falsely write prescriptions for Plavix under circumstances that did not comply with Medicaid's requirements. Second, Relator argues that each of the fifty states' Medicaid plans also imposes a "medically necessity" requirement. To counter, Defendants maintain -- just as they did under Medicare -- that Medicaid does not deny the reimbursement of a FDA approved prescription drug for its on-label use. Defendants submit that in the absence of kickbacks, reimbursement for a drug prescribed for an FDA-approved indication, i.e. an on-label prescription, cannot also be the basis for a claim under the FCA in the context of Medicaid. Moreover, Defendants contend that the states' Medicaid plans do not impose an additional "medically necessary" requirement as a precondition for payment for on-label drug prescriptions.

To begin, the Medicaid Act, 42 U.S.C. § 1396 *et seq.*, established the Medicaid program which is separate from the Medicare program. Under the Medicaid Act, the federal government and the states jointly fund the Medicaid program, with the federal government contributing approximately between 50% and 83% of the funding, with the states responsible for the rest. 42 U.S.C. § 1396d(b); *Pennsylvania Medical Soc. v. Snider*, 29 F.3d 886, 888-89 (3d Cir. 1994). Eligibility for Medicaid benefits is based on need. *Id.* "A state is not required to participate in the Medicaid program, but if it decides to participate, it must comply with the Medicaid Act and its implementing regulations." *Snider*, 29 F.3d at 889 (citing 42 U.S.C. § 1396c). A

participating state must propose a plan that meets certain statutory requirements set forth in § 1396a(a). For such a plan to become effective, the plan must be approved by the Secretary of the HHS. *See* 42 U.S.C. § 1396a(b).

"To gain payment under Medicaid for covered drugs, a manufacturer must enter a standardized agreement with HHS; in the agreement, the manufacturer undertakes to provide rebates to States on their Medicaid drug purchases." *Astra USA, Inc. v. Santa Clara County*, 131 S. Ct. 1342, 1346 (2013) (citing 42 U.S.C.A. § 1396r-8(a)); *see United States ex rel. Schumann v. AstraZeneca Pharms. L.P.*, 769 F.3d 837, 841 (3d Cir. 2014). "Once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003) (citing 42 U.S.C. § 1396r-8(d)). For example, a State may exclude coverage for drugs such as "agents . . . used for cosmetic purposes or hair growth." 42 U.S.C. § 1396r-8(d)(2)(C). Here, Relator has not alleged that Plavix, during the relevant time period, was on any state or federal exclusion lists.

Importantly, similar to Medicare's requirement, the Medicaid statue is clear that a plan participant will receive reimbursements only for a "covered outpatient drug." *United States ex rel. Campie v. Gilead Sci., Inc.*, No. 11-941, 2015 U.S. Dist. LEXIS 77261, at *17 (N.D. Cal. Jun. 12, 2015). Identical to Medicare's definition, all drugs approved as safe and effective by the FDA since 1962 qualify as "covered outpatient drugs" under Medicaid. *See* 42 U.S.C. § 1396r-8(k)(2); *United States ex*

rel. Conrad v. Abbott Labs., Inc., No. 02-11738, 2013 U.S. Dist. LEXIS 26048, at *10 (D. Mass. Feb. 25, 2013) (finding that "[a]ll drugs approved as safe and effective by the FDA since 1962 qualify as covered outpatient drugs" under Medicaid); *Campie*, 2015 U.S. Dist. LEXIS 77261, at *17; *In re Rezulin Products Liab. Litig.*, 524 F. Supp. 2d 436, 439 (S.D.N.Y. 2007); *United States v. Ortho-McNeil Pharm., Inc.*, No. 03-8239, 2007 WL 2091185, at *2 (N.D. Ill. Jul. 20, 2007); *United States ex rel. Conrad v. Healthpoint, Ltd.*, No. 02-11738, 2012 WL 1004775, at *1 (D. Mass. Mar. 26, 2012); *Rostholder*, 745 F.3d at 701. Indeed, also like Medicare, Medicaid reimburses "covered outpatient drugs" that are prescribed for a "medically accepted indication," which is defined as "any use for a covered outpatient drug . . . approved under the [FDCA]." *See* 42 U.S.C. § 1396r-8(k)(6). Accordingly, during the relevant time period, Plavix was considered a "covered outpatient drug" reimbursable under Medicaid. Therefore, I reject Relator's argument that under the federal Medicaid act, a drug prescribed for its on-label, FDA-approved use can be found to be not "medically necessary."

Relator nonetheless argues that the requirement that a drug be a "covered outpatient drug" is merely a prerequisite to payment coverage, and that state Medicaid plans additionally require, pursuant to 42 C.F.R. § 440.230(d), that a prescribed drug also be "medically necessary." Indeed, the TAC cites to authority[14]

[14] Relator cites to statutes and regulations, and also to manuals provided by state agencies to Medicaid providers. Defendants have not argued that such manuals are non-binding and therefore cannot be used as a basis to show that a state requires medical necessity before a Medicaid service is covered. Such an argument would be fruitless, however, as such manuals are "interpretive rules," and similar Medicare

from all fifty states indicating that each state's Medicaid plan will only cover services[15] which are medically necessary. *See* TAC at ¶¶ 52–102. "Medical necessity," Relator alleges, is to be determined in the first instance by the treating physician. In that regard, Relator argues that Defendants' misrepresentations of the effectiveness of Plavix prevented physicians from making this determination accurately, and that these misrepresentations caused physicians to falsely conclude that Plavix was a medically necessary drug eligible for Medicaid coverage.

In response, Defendants maintain that states do not possess the authority to impose a "medical necessity" requirement under Medicaid, and therefore, a medical necessity requirement would violate federal law. Rather, Defendants submit that Medicaid only authorizes the states to limit the "amount, duration, and scope" of coverage, and in that connection, the state Medicaid provisions relied upon by Relator, only allow for limitations that are consistent with federal law, but do not supersede the federal requirement that on-label prescriptions of FDA approved drugs are reimbursable under Medicaid.[16] In support of their position, Defendants rely on *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1330–31 (S.D. Fla. 2006), for the

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manuals have been the basis for "numerous cases imposing FCA liability, and even criminal false claims liability." *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318, 351 (D. Conn. 2004).

[15] 42 C.F.R. § 440.1 *et seq.* defines various "services" within the Medicaid law; "services" includes "prescribed drugs." 42 C.F.R. § 440.120(a).

[16] Notably, Defendants do not, however, claim that the state requirements are preempted; rather, Defendants maintain that the states' requirements compliment the federal standard under Medicaid.

proposition that a state imposed "medical necessity" requirement would violate federal law and that states may only remove Medicaid-eligible drugs from coverage in four specific circumstances detailed in the Medicaid statute.

Before I discuss *Edmonds*, I must first discuss the states' authority in limiting prescription drug coverage under Medicaid. Under federal law, states choosing to participate in Medicaid must provide a core set of mandatory services to qualified beneficiaries. *See id.*; 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a). For example, state Medicaid plans must provide coverage to qualified beneficiaries for "inpatient hospital services" and "laboratory and X-ray services." *Id.* at §§ 1396a(a)(10)(A), 1396d(a)(1), (3). In addition to those mandatory services, "a state may also elect to cover other categories of services." *NB v. District of Columbia*, No. 14-7054, 2015 U.S. App. LEXIS 12351, at *3-4 (D.C. Cir. Jul. 17, 2015). Those optional services then become part of the state's Medicaid plan, in which event the optional services become subject to the requirements of federal law. *Doe 1-13 ex rel. Doe, Sr. 1-13 v. Chiles*, 136 F.3d 709, 714 (11th Cir. 1988). Indeed, prescription drug coverage is one of those optional services. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(12); *NB*, 2015 U.S. App. LEXIS, at *4.

When a state elects to cover prescription drugs, it can limit or condition coverage in certain ways. First, Medicaid permits participating states some leeway to determine which classes of prescription drugs to cover. *Id.* at *5. The statute specifies categories of drugs that a state may entirely "exclude[] from coverage." 42 U.S.C. § 1396r-8(d)(2). Second, for non-excluded drugs, Medicaid enables a state to

limit the circumstances under which it will provide coverage. A state may, for example, subject a drug to "prior authorization" requirements. 42 U.S.C. § 1396r-8(d)(1)(A). Additionally, states may exclude or otherwise restrict a covered outpatient drug if: (1) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6)); (2) the drug is contained in the list referred in 42 U.S.C. § 1396r-8(d)(2); (3) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary; or (4) the State has excluded coverage of the drug from its formulary. *See* 42 U.S.C. § 1396r-8(d)(1)(B)(i) – (iv).

The district court in *Edmonds* was confronted with the issue whether a state's imposition of certain requirements restricting prescription drug coverage exceeded the state's authority under Medicaid. In that case, the plaintiffs sued the Florida Agency for Health Care Administration, which had determined that Neurontin, a drug used to treat, *inter alia*, seizures, was only covered for "two FDA-approved uses, and [only] for off-label uses . . . [which were] substantiated as being safe and effective by double-blind, placebo-controlled, randomized clinical trials." *Edmonds*, 417 F. Supp. 2d at 1331. All other off-label uses were excluded from Medicaid coverage entirely. *Id.* Referring to states' authority provided in 42 U.S.C. § 1396r-8(d)(1)(B) -- as outlined above -- the *Edmonds* court first explained that "the [Medicaid's] statutory scheme is carefully constructed in such a way to precisely circumscribe the only methods by which a state may remove a Medicaid-eligible drug from coverage and prevent it from either arbitrarily removing a drug or adopting its own *ad hoc* procedure for removing a drug from coverage." *Id.* at 1330–31. In that regard, the

court dealt only with the question of "whether the disputed uses are for medically accepted indications." *Id.* at 1327. The court found that the state's interpretation of "medically accepted indication" -- which completely excluded from Medicaid coverage all off-label uses that were not substantiated by clinical trials -- was not congruent with federal law, and therefore, could not be used to categorically exclude a drug from coverage. *Id.* at 1337.

I do not find *Edmonds* applicable here. First, unlike the State of Florida in *Edmonds,* which attempted to place certain restrictions on a particular drug in violation of federal law, there are no allegations here that Plavix was restricted, or excluded, from coverage by any states' Medicaid plans. Indeed, Relator does not allege that the state statutes or regulations categorically exclude Plavix, or certain uses of Plavix, from Medicaid coverage. Rather, Relator alleges that Plavix was not "medically necessary" under those states' plans and that, absent Defendant's false marketing, physicians would have concluded that Plavix was unnecessary and not cost-effective.

That said, there is no dispute that federal law permits states to place reasonable restrictions on prescription drugs covered by Medicaid. 42 U.S.C. §§ 1396r-8(d)(1), (5); 42 C.F.R. § 440.230(d); *NB v. District of Columbia*, 34 F. Supp. 3d 146, 153 (D.D.C. 2014), *rev. on other grounds*, *NB v. District of Columbia*, 2015 U.S. App. LEXIS 12351 (D.C. Cir. July 17, 2015). However, "[a] State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan . . . which are consistent with the

objectives of this subchapter [of Medicaid]," 42 U.S.C. § 1396a(a)(17), and the implementing regulation requiring that each provided service, including prescription drugs, "must be sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b); *Detgen v. Janek*, 752 F.3d 627, 631 (5th Cir. 2014). That requirement has been interpreted by the Supreme Court to include certain reasonable restrictions relating to costs, *see Walsh*, 538 U.S. at 666 and *Beal v. Doe*, 432 U.S. 438, 444 (1977), albeit budgetary considerations cannot be "the conclusive factor in decisions regarding Medicaid." *Arkansas Med. Soc., Inc. v. Reynolds*, 6 F.3d 519, 531 (8th Cir. 1993); *Bontrager v. Indiana Family & Soc. Servs. Admin.*, 697 F.3d 604, 611 (7th Cir. 2012); *Tallahassee Mem'l Reg'l Med. Ctr. v. Cook*, 109 F.3d 693, 704 (11th Cir. 1997).

Here, the TAC cites to authority from all fifty states indicating that each state's Medicaid plan will only cover services which are medically necessary. *See* TAC at ¶¶ 52–102. The majority of the states, as alleged, simply include "medical necessity" as a condition for reimbursement.[17] However, Relator has not alleged how those states have defined "medical necessity"; in other words, there are no allegations relating to the types of restrictions that have been placed on prescription drug coverage by those

[17] According to Relator, thirty-three states, including the District of Columbia, have added the term "medical necessity" to their state Medicaid statutes. However, Relator has specifically alleged that the following state Medicaid statutes include in their definition of "medically necessary" a requirement that treatment additionally be cost effective: Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington and Wyoming. *See* TAC ¶¶ 58, 59, 64, 68, 72, 73, 76, 78, 79, 85, 87, 88, 91, 93, 96, 99, 102. I will refer to these states as the "Cost-Imposed States."

states during the relevant time period. Indeed, as I have explained above, without any specific restrictions by a state, on the face of the federal Medicaid statute, a drug that has been approved by the FDA, such as Plavix, is considered a "covered outpatient drug" reimbursable under Medicaid when that drug is prescribed for its on-label use. In that connection, while Relator asserts that Plavix may not be as safe or effective as other drugs, such as aspirin, she does not explain why this distinction would exclude Plavix from coverage as medically unnecessary, particularly since the FDA has approved Plavix for the uses prescribed by doctors here. Accordingly, Relator has not sufficiently alleged a FCA claim as to any of the thirty-three states, including the District of Columbia.

The allegations based on the Medicaid plans of the Cost-Imposed States stand on a different footing. Relator alleges that the Cost-Imposed States have included in their Medicaid statutes a cost effective requirement. In that connection, Relator alleges that Plavix is no more effective than aspirin, which is significantly less costly. *See* TAC at ¶¶ 115–120. Because, as Relator avers, "Plavix was regularly and systematically presented to physicians as superior to aspirin for [certain] patients," *see id.* at ¶ 152, Defendants caused these physicians to submit false claims. At this stage of this litigation, I find that Relator has stated plausible claims under the Cost-Imposed States' Medicaid regime. Relator alleges that cost-effectiveness is a "condition[] of Government payment"—that is, a condition "which, if the government knew they were not being followed, might cause it to actually refuse payment." *Wilkins*, 659 F.3d at 309. Indeed, the state statutes and regulations cited by Relator,

on their face, indicate that services and treatments must be cost-effective in order to be covered by Medicaid. In response, Defendants summarily argue that the states cannot override the federal mandate that on-label prescriptions be reimbursed. Again, for support, Defendants rely on the *Edmonds* decision, which I have already distinguished. Other than *Edmonds*, Defendants have not relied on any other case law to support their position. As I have outlined above, states have the authority to impose certain restrictions based on cost, albeit those impositions must not be the sole consideration under the states' Medicaid plans. It appears, pursuant to Relator's allegations, that the Cost-Imposed States have included not only a cost-based restriction, but rather, those states have also mandated that the cheaper alternative must be equally effective as Plavix. *See, e.g.*, *Detgen ex rel. Detgen v. Janek*, 752 F.3d 627, 632 (5th Cir. 2014). And, these restrictions, as alleged, appear to be consistent with the limitations authorized by Medicaid.

That said, however, I note that the Medicaid statutory scheme – particularly with respect to the states' authority – is complex. Indeed, Relator's claims in this context may not survive scrutiny should, for example, evidence show that Plavix was placed on certain states' Preferred Drug Lists. *See Iowa Dep't of Human Servs. v. Ctrs. for Medicare & Medicaid Servs.*, 576 F.3d 885, 887 (8th Cir. 2009) (explaining that doctors may prescribe to Medicaid patients [drugs on a state's Preferred Drug List] without having to obtain prior authorization from the state."); *NB*, 2015 U.S. App. LEXIS 12351, at *4. As such, I make no comment on the ultimate viability of

Relator's claims in this regard. Simply, I find here that Relator's allegations in this context are sufficient to pass Rule 12(b)(6) muster.

Accordingly, with respect to Medicaid in the states of Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington, and Wyoming, Relator has stated a claim under the FCA. As to the remaining states, including the District of Columbia, however, Relator's FCA claims are dismissed for failure to state a claim.

3. *Formulary Allegations*

In connection with the FCA claims, the TAC additionally alleges that Defendants violated the FCA by "dup[ing] each state's Medicaid program into including Plavix on its formulary." TAC at ¶ 49. A formulary is "a list of Medicaid-eligible drugs for which the state will provide reimbursement when prescribed for medically accepted indications." *Edmonds*, 417 F. Supp. 2d at 1328; *see* 42 U.S.C. § 1396r-8(d)(4). The formulary must be "developed by a committee consisting of physicians, pharmacists, and other appropriate individuals." 42 U.S.C. § 1396r-8(d)(4)(A). Generally, a formulary is required to include "the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section."[18] *Id.* However, the committee may exclude a Medicaid-eligible drug from the formulary "with respect to the treatment of a specific disease

[18] Subsection (a) requires manufacturers to "enter[] into and have in effect a rebate agreement" with the state for each covered drug as a precondition of Medicaid coverage. 42 U.S.C. § 1396r-8(a).

or condition for an identified population (if any) only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary." 42 U.S.C. § 1396r-8(d)(4)(B). The TAC asserts that "each states' Medicaid program would have excluded Plavix . . . from its Medicaid formulary, but for the false marketing scheme perpetuated by DMS/Sanofi to mislead the states into believing Plavix was more effective than aspirin for certain indications." TAC at ¶ 132. Thus, according to the TAC, "[e]ach time a claim was submitted to the federal government for Plavix on the basis of Plavix being on a state Medicaid formulary, it constituted a false claim." *Id.* at ¶ 186.

Defendant argues that, with regard to the formulary allegations, Relator "has not and cannot identify any false certification which actually was a prerequisite to payment." Def Br. at 11. Additionally, Defendant contends that "Relator's assertions about hypothetical decisions by Medicaid or Medicare Part D P&T committees fail to state a claim because they are wholly speculative." *Id.* at 12. Because the committees are required to "evaluate independently the clinical data and information," Defendants contend that Relator has not alleged how the purportedly false marketing was material to the committees' decisions on formularies. To counter, Relator insists that her claims are not hypothetical, because the Pharmacy and Therapeutics Committees 'are comprised of doctors and pharmacists—the very individuals targeted by Defendants in their scheme." Rel. Opp. at 14. In that respect, Relator

reasons that the facts "about how Defendants misled the doctors and pharmacists are equally applicable in this context." *Id.* I disagree with Relator's position.

Crucially, in order to state a claim under the FCA, a plaintiff must first allege that a false claim was made. *See Wilkins*, 659 F.3d at 305. Here, while Relator alleges that a false claim was made by a physician each time that a prescription for Plavix was reimbursed on the basis of Plavix's status on a state formulary, these reimbursement claims could not be false because Plavix was already placed on each state's formulary. Put differently, Relator cannot identify any false certification which actually was a prerequisite to payment. Equally deficient, Relator's speculative allegations with respect to Medicaid P&T Committees also do not state a claim. There are simply no allegations how any of Defendants' allegedly false promotional statements were material to, or had any bearing on, the decisions made by these committees.

Nevertheless, in her opposition papers, Relator maintains that the false claim arose when "Plavix was reimbursed because of its status on the formulary, and thus deemed 'medically necessary' by the Medicare or Medicaid program." Rel. Opp. at 15; *see also* TAC at ¶ 24–25 (alleging that Defendants' scheme "caused states to include Plavix on their state's Medicaid formularies for indications for which Plavix is not medically necessary," thus causing reimbursements pursuant to a formulary to be false claims). However, this additional allegation is substantively the same with regard to Relator's theory of liability under Medicaid and Medicare Part D elsewhere in the TAC – which theory I have already rejected. Hence, the additional averments

that Plavix is medically unnecessary under these Medicaid formularies do not create a separate claim. Thus, to the extent that Relator's claim is based solely on the formularies' inclusion of Plavix as a result of Defendants' allegedly false or misleading marketing, Relator has not sufficiently alleged that a false certification was made. To the extent that Relator alleges that reimbursements pursuant to a formulary were not "medically necessary," Relator's allegations have been rejected.

Having dismissed all claims except for those brought with respect to Medicaid coverage in those states which include a requirement that treatment be cost-effective—namely, Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington, and Wyoming—the remainder of this opinion will apply only to those claims remaining. In addition, Defendants have argued that Relator's claims under the conspiracy provision of the FCA, and the state FCA claims must be dismissed for the same reasons. I agree, except, again, for the states which include a cost-effectiveness provision in their Medicaid requirements. Of these states, Relator has asserted claims under the state-equivalent FCAs of Delaware, Montana, Massachusetts, Rhode Island, Oklahoma, North Carolina, and Connecticut; these claims are not dismissed. All the remaining state law counts are dismissed for failure to state a claim.

D. Pleading Deficiencies under Rules 8 and 9(b)

Defendants argue that the TAC "suffers from fatal pleading deficiencies that should mandate dismissal pursuant to Rules 8(a) and 9(b) of the Federal Rules of Civil Procedure." Def. Br. at 13. Defendants assert that Relator

> fails to identify: (i) a single physician to whom a misrepresentation was made; (ii) a single instance (date, time, and location) in which she or any other sale representative made an alleged misrepresentation; (iii) a single physician that prescribed Plavix as a result of such a misrepresentation; or (iv) any Medicaid or Medicare beneficiary that that received and filled such a prescription.

Id. at 14. Defendants additionally assert that "Relator fails to provide a single well pleaded factual allegation that even one doctor submitted a prescription for an FDA-approved indication for Plavix that was not necessary for a patient. *Id.* Finally, Defendants argue that Relator's formulary allegations are deficient, because they are "based on 'information and belief'" but do not set forth the factual basis for such belief. *Id.* at 15.

In their Motion to Dismiss the Second Amended Complaint, filed in the transferor court, Defendants argued that Relator failed to identify:

> One single physician to whom a particular misrepresentation was made, any instance in which she or any other sale representative made any alleged misrepresentation, any physician that prescribed the drug as a result of such a misrepresentation, any Medicare beneficiary that that received and filled such a prescription, or any pharmacist that filled such a prescription.

Motion to Dismiss Second Amended Compl., Def. Br. at 24. Defendants also argued in that Motion that "Relator's failure to allege any detail identifying a claim

submitted by a doctor or pharmacy for reimbursement of Plavix under Medicare or Medicaid thus requires dismissal here." *Id.* at 23.

Chief Judge Herndon denied Defendants' Motion to Dismiss under Rule 9(b). *See* January 2013 Memorandum and Order. With regard to Defendants' assertions that the Second Amended Complaint was insufficient under Rule 9(b), Chief Judge Herndon stated that "Relator's instant allegations are sufficient to comport with the requirements of Rule 9(b) in this instance," and that "[a]s to which specific physicians such misrepresentations were allegedly made, and further which specific employees of defendants' instructed relator to make such misrepresentations, such details can be fleshed out in discovery." *Id.* at 8–9. In response to Defendants' arguments that "relator is required at this stage in the proceedings to identify specific claims actually submitted which relator alleges were false," the court stated that it "does not feel such specificity is required in this instance." *Id.* at 9 n.6.

While the Third Amended Complaint has added significant details as to the states' limitations on Medicaid and Medicare, *see* TAC at ¶¶ 52–102, and as to the states' formulary programs, *see* TAC at ¶¶ 132–183, the factual allegations otherwise remain the same as alleged in the Second Amended Complaint. Thus, with the exception of the Defendants' new arguments regarding the formulary allegations, Chief Judge Herndon's decision regarding the adequacy of Relator's pleading remains the law of the case.

"The law of the case doctrine directs courts to refrain from re-deciding issues that were resolved earlier in the litigation." *Pub. Interest Research Grp. of New*

Jersey, Inc. v. Magnesium Elektron, Inc., 123 F.3d 111, 116 (3d Cir. 1997). The rule was developed "to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit." *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009) (internal quotation marks and citation omitted). Law of the case is a matter of a court's discretion, but a court faced with revisiting a prior decision in the case "should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would make a manifest injustice." *Id.* (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)). In addition, a court may revisit its own decisions or one of a coordinate court where (1) new evidence is available; (2) "a supervening new law has been announced"; or (3) "whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result." *Id.* The law of the case doctrine, however, only applies "to issues that the court actually decided, whether expressly or by implication." *Coca-Cola Bottling Co. of Shreveport v. Coca-Cola Co.*, 988 F.2d 414, 429 (3d Cir. 1993).

Here, two of Defendants' arguments were previously argued and expressly decided by the transferor court in this case. Indeed, these arguments were not raised in Defendants' previous motion for reconsideration before this Court, and therefore, the section of the transferor court's opinion on these issues was not disturbed. None of the "extraordinary circumstances" which merit a court revisiting a prior decision apply here. Thus, I decline to revisit this issue, and hold that, in accordance with

Chief Judge Herndon's previous decision, Relator's claims are adequate under Rule 9(b).[19]

Defendants have raised one new issue, namely that Relator's formulary allegations are insufficient. However, I have already determined that Relator's formulary allegations fail to state a claim, *supra*. Therefore I need not address this argument.

E. Statute of Limitations

1. *Federal Statute of Limitations*

The FCA states that:

> A civil action under section 3730 may not be brought—
>
> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed
> whichever occurs last.

31 U.S.C. § 3731(b).

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[19] I note, moreover, that when applying the standard of Rule 9(b) to claims under the FCA, the Third Circuit, like the First, Fifth, and Ninth Circuits, uses a "nuanced" version of the heightened pleading standard. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157 (3d Cir. 2014). Under this reading "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 156. The court also repeated the statement from *Wilkins* that "we ha[ve] never held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief." *Id.* Thus, Defendants' argument that the Complaint must identify specific false claims is misplaced.

Defendants argue that the six-year statute of limitations requires that the "allegations regarding Defendants' alleged false statements . . . be limited to conduct occurring after March 30, 2005." Def. Br. at 24. Relator argues that the three year provision applies to claims brought by relators, and that there "is no indication on the face of the complaint that the Government should have known about the fraud more than three years before this action was brought." Rel. Opp. at 36. Defendants, in response, contend that the three-year provision "does not apply when, as here, the Government declines to intervene." Def. Repl. at 8.

The Third Circuit has not stated definitively whether the three-year tolling provision applies to claims brought by relators. *But see United States ex rel. Malloy v. Telephonics Corp.*, 68 Fed. App'x 270, 273 (3d Cir. 2003) (stating that the time a relator became aware of fraud "is important, because it determines whether we apply the six year statute of limitations in § 3731(b)(1), or the three year limitation in § 3731(b)(2)"). Other circuit courts have divided on the issue. *Compare United States ex rel. Sanders v. North Amer. Bus Indus., Inc.*, 546 F.3d 288, 293–96 (4th Cir. 2008) (holding that three-year tolling provision does not apply where Government does not intervene); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 725 (10th Cir. 2006) (same) *with United States ex rel. Hyatt v. Northrop Corp.*, 91 F.2d 1211, 1216 (9th Cir. 1996) (holding that three-year tolling provision applies "to *qui tam* plaintiffs as well as to the government").[20] However, district courts in this

[20] Where the tolling provision has been held to apply to suits brought by *qui tam* plaintiffs, "the three-year extension of the statute of limitations begins to run once

circuit have held that the three-year tolling provision only applies when the Government chooses to intervene in a FCA case. *United States ex rel. Silver v. Omnicare*, No. 11-1326, 2014 WL 4827410, at *8 (D.N.J. Sept. 29, 2014) ("A plain reading of the statute compels the conclusion that a FCA claim must be filed within six years, or if the U.S. government intervenes, the limitations period is extended for three years"); *United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2014 WL 1418293, at *12 (D.N.J. April 11, 214) (applying only the six year limitation period to *qui tam* action); *United States ex rel. Bauchwitz v. Hollomon*, 671 F. Supp. 2d 674, 694–95 (E.D. Pa. 2009) ("we conclude that the three-year tolling period in § 3731(b)(2) does not apply in cases where the government does not intervene."). These cases have followed the logic of the United States Supreme Court, in *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009), which held that, for the purposes of Fed. R. App. P. 4, the United States is not a party to a *qui tam* FCA action unless it chooses to intervene.

I agree with the other courts in this Circuit. As the Fourth Circuit noted: "Section 3731(b)(2) refers only to the United States—and not to relators." *Sanders*, 546 F.3d at 293. To read the statute as permitting the three year tolling provision to apply to relator's suits would "produce the bizarre scenario in which the limitations

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qui tam plaintiff knows or reasonably should have known the facts material to his right of action." *Hyatt*, 91 F.2d at 1217–18; *see also Malloy*, 68 Fed. App'x at 273 (asking when relator knew of fraud for purpose of determining whether six year or three year provisions applied). Relator's statement that the statute of limitations had not run because the Government could not have known about the fraud more than three years before she brought suit is incorrect in any jurisdiction.

period in a relator's action depends on the knowledge of a nonparty to the action." *Id.* I, therefore, find that the six year statute of limitations applies here, as the United States has declined to intervene. Thus, to the extent that Relator alleges that Defendants' conduct resulted in the filing of false claims prior to March 30, 2005, six years prior to the filing of the initial Complaint, such claims are dismissed.

2. *State Statute of Limitations*

The only remaining state law FCA claims are those of Delaware, Montana, Massachusetts, Rhode Island, Oklahoma, North Carolina, and Connecticut. Of these, the following states have statutes of limitations which track the language of the Federal False Claims Act in providing a six year statute of limitations, and a tolling provision based on when a state official knew or should have known of the facts underlying the action: Delaware (Del. Code. tit. 6 § 1209(a)(1)); Massachusetts (Mass. Gen. Laws ch. 12, § 5K); Montana (Mont. Code Ann. § 17-8-404(1)); North Carolina (N.C. Gen. Stat. § 1-615(a)); Oklahoma (Okla. Stat. Ann. § 63-5053.6(B)(1)); and Rhode Island (R.I. Gen. Laws § 9-1.1-5(b)).[21] Neither party has argued that any of these statutes should be read differently than the federal statute; accordingly, as with the federal claims, to the extent that Relator alleges that Defendants' conduct resulted in the filing of false claims prior to March 30, 2005, six years prior to the filing of the initial Complaint, such claims are dismissed.

F. State Claims

[21] Defendants have not raised the statute of limitations for any other state to which the remaining claims apply.

Defendants argue, in vague terms, that Relator's remaining state FCA claims should be dismissed for several reasons. First, Defendants argue that Relator's claims under the state or local statutes that "are substantially similar to and/or track the language of the federal FCA must likewise be dismissed," on the basis of the public disclosure bar. Def. Br. at 25 and n. 21. However, as described *supra*, I have determined that Relator is an original source within the meaning of the federal statute, as applied to conduct occurring before 2010, but that Relator's claims involving conduct after 2010 must be dismissed under the federal public disclosure bar. As Defendants have not suggested that the state claims would be analyzed differently, the same result applies.

Next, Defendants assert that Relator failed to comply with the *qui tam* provisions of the various state false claims acts because she "fails to allege she provided all material evidence in support of her claims or served her complaint on any state other than Illinois." *Id.* at 25–26. Indeed, where "plaintiffs here have failed to comply with every pre-condition required by state false claims acts," the state claims must be dismissed. *United States ex rel. Fowler v. Caremark RX, Inc.*, Civ. No. 03-8714, 2006 WL 1519567, at *5 (N.D. Ill. May 30, 2006). However, the statutes cited by defendant are not pleading requirements, but procedural requirements. The statutes require that the Complaint be served upon the states after filing. *See, e.g.*, Del. Code Tit. 6 § 1203(b)(2), Mass. Gen. Laws ch. 12 § 5C(3), N.C. Gen. Stat. § 1-608(b)(2). However, there is no evidence on this record that Relator has not complied with these state procedural requirements. In fact, the docket of this case reflects that

Summonses were returned executed by various states. *See* Docket # 30-33. That being said, should Defendants discover that Relator has failed to comply with these service provisions, Defendants may then move to dismiss on that basis.

Third, Defendants argue that Connecticut, Delaware, Massachusetts, and North Carolina permit a relator to bring *qui tam* actions only in the states' own courts. However, 31 U.S.C. § 3732(b) provides that "[t]he district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730." Furthermore, the Eastern District of Pennsylvania has squarely rejected Defendants' argument, based on 31 U.S.C. § 3732(b) and the principles of supplemental jurisdiction. *United States ex rel. Galmines v. Novartis Pharmaceuticals Corp.*, No. 06-3213, 2013 WL 5924962, at *2–6 (E.D. Pa. Nov. 5, 2013). Finally, there are numerous federal actions which have been brought under these states' false claims provisions; Defendants have not pointed to any cases that have been dismissed because the state statute does not permit the suit to be brought in federal court. *See United States ex rel. Ruscher v. Omnicare, Inc.*, No. 08-3346, 2014 WL 2618158, at *28 (S.D. Tex. June 12, 2014) (Defendants' sole support for their assertion that state FCA claims must be filed in state courts was withdrawn, motion therefore denied).

Fourth, Defendants assert that nineteen of the state law claims should be dismissed to the extent that the counts are based on "allegedly false claims submitted prior to the relevant state law's effective date where the statutes do not permit

retroactive application" or "where applying the laws retroactively would violate the ex post facto clause of the United States Constitution." Def. Br. at 26–27. Of these nineteen state law claims, the claims under the laws of Connecticut, Delaware, Montana, Massachusetts, North Carolina, Oklahoma, and Rhode Island remain.

Initially, Defendants do not explain why retroactive application of the False Claims Act would violate the *Ex Post Facto* Clause. In order to determine whether a law violates the Ex Post Facto Clause, United States Const. Art. 1, § 10, cl. 1, a court must determine whether a law intended to establish civil or criminal proceedings. *Smith v. Doe*, 538 U.S. 84, 92 (2003). If the law provides for civil, nonpunitive proceedings, the court must determine whether the law is "so punitive either in purpose or effect as to negate the State's intention' to deem it 'civil.'" *Id.* On their face, all of the state False Claims Acts are civil. Defendants have provided no evidence that any of the state laws are punitive in either purpose or effect. I therefore decline to address this argument further.

Moreover, Defendants merely cite to the state statutes and their effective dates. The cited statutes do not state whether they are retroactive, and Defendants do not point to case law or other authority explaining whether these statutes can or cannot be applied retroactively. Defendants, as the moving party, have "the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). This argument is therefore denied without prejudice.

IV. Motion for Reconsideration

During the pendency of this Motion to Dismiss, Relator also filed a Motion for Reconsideration of this Court's denial of Relator's Motion for Suggestion of Remand to the United States District Court for the Southern District of Illinois. Relator suggests that because two similar cases, *Hood ex rel. Mississippi v. Bristol Myers Squibb Co.*, Civ. No. 13-5910, and *West Virginia ex rel. McGraw v. Bristol Myers Squibb Co.*, Civ. No. 13-1603, have been transferred to other jurisdictions, her action "now stands alone in stark contrast to the eighty-three other personal-injury actions that . . . are now consolidated before this Court for pretrial proceedings." Mot. for Recon. at 4.

The multidistrict litigation statute provides that "[w]hen civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings" 28 U.S.C. § 1407(a). The judicial panel on multidistrict litigation may transfer such a case "upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." *Id.*

The MDL panel which transferred this case to the District of New Jersey noted, in response to Relator's opposition to the transfer, that, like the present case, "[t]he complaints in the personal injury actions also contain numerous allegations that defendants improperly marketed Plavix." *In re Plavix Mktg., Sales Practices & Products Liab. Litig. (No. II)*, 923 F. Supp. 2d 1376, 1379 (U.S. Jud. Pan. Mult. Lit. 2013). Similarly, this Court, when deciding Relator's Motion for Suggestion of

Remand, found that between this case and the personal injury cases, "[t]here is an overlap of factual issues and there is no doubt about that." Mot. Hearing Aug. 21, 2013, at 8-12 to -13. The inclusion of this case as part of the MDL proceedings was not based on the other *qui tam* marketing suits, but rather on the commonalities between this action and the personal injury suits. These commonalities have not changed.

Moreover, the other two *qui tam* suits were remanded because this Court lacked subject matter jurisdiction over the state law *parens patriae* claims. *West Virginia ex rel. McGraw v. Bristol Myers Squibb Co.*, 2014 WL 7 93569 (D.N.J. June 3, 2014); *Hood*, Civ. No. 13-5910, Dkt No. 100 (July 22, 2014). There is no such issue in this case.

Accordingly, the Motion for Reconsideration is denied.

V. CONCLUSION

For the reasons expressed above, Defendants' Motion to Dismiss is granted in part and denied in part, as follows: Relator's claims under the federal FCA are dismissed, except to the extent the claims relate to state Medicaid plans, which have imposed a cost effective requirement, in the following states: Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington, and Wyoming. However, to the extent that Relator's remaining claims are based on allegations that Defendants' deceptive marketing practices caused Plavix to be placed on state Medicaid and Medicare formularies, those portions of the claims are

dismissed. In addition, pursuant to the statute of limitations, the federal claims are restricted to conduct which resulted in the making of false claims after March 30, 2005. All claims arising under state law are dismissed, except for the following states: Delaware, Montana, Massachusetts, Rhode Island, Oklahoma, North Carolina, and Connecticut. Those remaining state law claims are, like the federal claims, limited to conduct which resulted in the making of false claims after March 30, 2005.

Additionally, Relator's Motion for Reconsideration of this Court's denial of the Motion for Suggestion of Remand is denied.

An appropriate Order shall follow.

Date: August 20, 2015

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
United States District Judge